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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,721	03/01/2007	Ralf Himmelreich	075422-0015	3167

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

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09/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,721	Applicant(s) HIMMELREICH ET AL.	
	Examiner TERESA E. STRZELECKA	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-23 are pending and will be examined.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5-7, 9, 10 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneider (EP 0 442 026 B1).

Regarding claim 1, Schneider teaches a method of rapid isolation of nucleic acid, the method comprising:

- a) lysing the nucleic acid source (col. 2, lines 8-17),
- b) filtering the lysate through a porous matrix consisting of a material based on silica or of a silica coated material to bind the nucleic acid to the porous matrix in the absence of an alcohol and in the absence of a chaotropic salt (col. 2, lines 32-40),
- c) eluting the nucleic acid from the porous matrix of step b) by using an aqueous buffer solution (col. 3, lines 4-9).

Regarding claims 2 and 3, Schneider teaches genomic DNA (col. 1, lines 3-5).

Regarding claims 5 and 6, Schneider teaches blood, tissue, sperm, animal blood and tissues and vegetal cells (col. 1, lines 5-8).

Regarding claim 7, Schneider teaches lysing solution which does not contain a chaotropic salt or alcohol (col. 2, lines 8-17).

Regarding claims 9 and 10, Schneider teaches borosilicate glass filter (col. 2, lines 32-36).

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Regarding claims 14 and 15, Schneider teaches PCR (col. 2, lines 1-2).

Regarding claim 16, Schneider teaches centrifugation to eliminate cell debris (col. 2, lines 20-24).

Regarding claims 17 and 18, Schneider teaches performing washes of matrix using washing buffer before eluting DNA (col. 2, lines 47-58; col. 3, lines 1-3).

4. Claims 1-10 and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Colpan (US 6,277,648 B1).

Regarding claim 1, Colpan teaches a method of rapid isolation of nucleic acid, the method comprising:

a) lysing the nucleic acid source (col. 5, lines 3-5; col. 6, lines 34-36; col. 7, lines 4-6),

b) filtering the lysate through a porous matrix consisting of a material based on silica or of a silica coated material to bind the nucleic acid to the porous matrix in the absence of an alcohol and in the absence of a chaotropic salt (col. 2, lines 1-8; col. 5, lines 8-18; col. 6, lines 41-52; col. 7, lines 13-18),

c) eluting the nucleic acid from the porous matrix of step b) by using an aqueous buffer solution (col. 5, lines 21-23; col. 6, lines 57-58; col. 7, lines 29-31).

Regarding claims 2-4, Colpan teaches genomic DNA and size range from 1 to 50 kb (col. 1, lines 65-67).

Regarding claims 5 and 6, Colpan teaches bacteria and rat liver tissue (col. 4, line 66; col. 6, line 31; col. 8, line 66).

Regarding claim 7, Colpan teaches lysis buffer which does not contain chaotropic salt and ethanol (col. 5, lines 3-5; col. 6, lines 34-36; col. 7, lines 4-6).

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Regarding claim 8, Colpan teaches adding RNase to the lysis solution (. 5, lines 3-5; col. 6, lines 34-36; col. 7, lines 4-6).

Regarding claims 9 and 10, Colpan teaches porous silica membranes (col. 2, lines 1-7).

Regarding claims 17 and 18, Colpan teaches washing steps before eluting DNA from the matrix (col. 5, lines 19-21; col. 6, lines 52-57; col. 7, lines 18-22).

Regarding claim 19, Colpan teaches single column filter tube (Fig. 1-6).

Regarding claim 20, Colpan teaches multi-well filter plate 9col. 4, lines 58-62).

Regarding claim 21, Colpan teaches membrane assembled in multiple layers (Fig. 1).

Regarding claim 22, Colpan teaches pore sizes being different in the different layers (col. 2, lines 49-67).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (EP 0 442 026 B1).

Schneider teaches pore sizes between 5 and 15 microns (col. 2, lines 37, 38) but does not teach pore sizes between 0.2 and 3.2 microns.

However, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used filters with different pore sizes in the method of Schneider according to the size of DNA to be purified. It would have been prima facie obvious to perform routine optimization to determine optimal filter pore size, as noted in *In re Aller*, 105 USPQ 233 at

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235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection specific filter pore sizes was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan (US 6,277,648 B1).

Colpan teaches pore sizes between 5 and 300 microns (col. 2, lines 55-57), but does not teach pore sizes between 0.2 and 3.2 microns.

However, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used filters with different pore sizes in the method of Colpan according to the size of DNA to be purified. It would have been prima facie obvious to perform routine optimization to determine optimal filter pore size, as noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection specific filter pore sizes was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in

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any way as compared to the closest prior art.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (EP 0 442 026 B1) and Stratagene Catalog (p. 39, 1988).

A) Schneider teaches a method of DNA isolation using porous silica matrix, lysing buffer which does not contain alcohol or chaotropic salt and an elution buffer (col. 2, lines 8-17 and 32-40, col. 3, lines 4-9), but does not teach kits.

B) Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Schneider into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

9. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan (US 6,277,648 B1) and Stratagene Catalog (p. 39, 1988).

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A) Colpan teaches a method of DNA isolation using porous silica matrix, lysing buffer which does not contain alcohol or chaotropic salt and an elution buffer (col. 2, lines 1-8; col. 5, lines 3-5 and 21-23), but does not teach kits.

B) Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Colpan into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
September 24, 2009